DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

OrthoDiscovery Group LLC (D.B.A. CrossRoads Extremity Systems) January 16, 2015
Mr.Vernon Hartdegen
Senior Vice President of Operations
458 Distribution Parkway
Collierville, Tennessee 38017

Re: K143039
Trade/Device Name: CrossRoads Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 21, 2014
Received: October 22, 2014

Dear Mr. Hartdegen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*

K143039

Device Name

CrossRoads Screw System

Indications for Use *(Describe)*

The CrossRoads Screw System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# Section 8 - 510(k) Summary

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|---|---|
| **Date:** | 21 October 2014 |
| **Sponsor:** | OrthoDiscovery Group LLC (DBA CrossRoads Extremity Systems)<br>458 Distribution Parkway<br>Collierville, TN 38017 USA<br>Phone: 901.221.8406 |
| **Contact Person:** | Vernon Hartdegen, VP of Operations |
| **Trade Name:** | CrossRoads Screw System |
| **Common Name:** | Screw system |
| **Device Classification:** | Class II |
| **Regulation, Name:** | 888.3040, Smooth or threaded metallic bone fixation fastener |
| **Device Product Code:** | HWC |
| **Device Description:** | The CrossRoads Screw System is comprised of bone screws having various features in a variety of diameters and lengths to accommodate differing patient anatomy. |
| **Intended Use:** | The CrossRoads Screw System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device. |
| **Materials:** | The CrossRoads Screw System implant components are manufactured titanium alloy (ASTM F136) and stainless steel (ASTM F138). |
| **Predicate Devices:** | Dual-Thread and Lag Screws (Vilex Inc. – K014154)<br>Dart-Fire Small and Charlotte Snap-off Screws (Wright Medical Technology – K082320, K100359 and K133713)<br>M3-X Lag Screw (OsteoMed Corp. – K924018)<br>Cannulated Screws and QFX Screw (Smith & Nephew – K090675 and K111994)<br>Herbert™ and Cannulated Screw System (Zimmer, Inc. – K102903 and K112885) |
| **Substantial equivalence** | Theoretical analysis of the worst case CrossRoads screws was performed to predict torsional and pullout strengths for the subject and predicate devices. The results demonstrate the predicted performance of the CrossRoads screws is substantially equivalent to the predicate devices. |
| **Technological Characteristics:** | The CrossRoads Screw System possesses the same technological characteristics as the predicate devices. These include:<br>• predicted performance,<br>• implant grade materials, and<br>• basic design.<br>Therefore the fundamental scientific technology of the CrossRoads Screw System devices is the same as previously cleared devices. |
| **Conclusion:** | The CrossRoads Screw System possesses the same intended use and technological characteristics as the predicate devices. Therefore the CrossRoads Screw System is substantially equivalent for its intended use. |